

"We hold that the trial court did not err in entering the default decree upon proper motion by the Government and notice to claimant.³

"The judgment and decree of condemnation is AFFIRMED."

Thereafter, the claimant filed a petition for writ of certiorari with the United States Supreme Court, which petition was denied on 6-29-59 (360 U.S. 931). The article and the accompanying circulars were subsequently destroyed in accordance with the terms of the decree of condemnation.

DRUG IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6005. Tranquil. (F.D.C. No. 3987L S. Nos. 60-309 M, 60-361 M.)

QUANTITY: 317 btls. at Detroit, Mich.

SHIPPED: 12-26-56 and 1-25-57, from Chicago, Ill., by State Pharmacal Co.

LABEL IN PART: "Tranquil * * * Alva Laboratories * * * Active Ingredients:

Each Tranquil contains in grams: Scopolamine Aminoxide Hydrobromide .00010; Methapyraline Hydrochloride N. N-Dimethyl-N'(2 Phenyl)-N'(2-Pyridyl)-Ethylenediamine Hydrochloride; Bromides; Sodium .09700, Potassium .19400, Ammonium .03285; Niacin; Niacinamide; Thiamine Hydrochloride; Riboflavin; Cyanocobalamin; Stomach and Liver whole desiccated (containing entire B Complex); Ferric Pyrophosphate, Acetanilid .05000; * * * Tranquil is Multiaction and embodies recent scientific developments in reducing nervous tension."

ACCOMPANYING LABELING: Leaflet in each bottle entitled "TRANQUIL—An aid in relief of nervous tension"; leaflets for druggists entitled "MR. DRUGGIST"; and display cartons reading in part: "Safe TRANQUILIZING AID."

LIBELED: 2-15-57, E. Dist. Mich.; amended libel 6-8-59.

CHARGE: 502(a)—when shipped, the name of the article "*Tranquil*" and the labeling of the article contained false and misleading representations that the article was one of the recently developed "tranquilizing" drugs and that it would produce all of the effects capable of being produced by a true "tranquilizer" drug; 502(c)—the ingredient statements required by 502(e)(2), and the warnings required by 502(f)(2), to appear in the labeling of the article were not prominently placed thereon with such conspicuousness and in such terms, as to render the required ingredient statements and warnings likely to be read and understood by the ordinary individual under customary conditions of purchase and use; 502(f)(2)—the labeling of the article failed to warn that frequent or continued use of the article may cause serious blood disturbances and mental derangement, and that the article should not be taken by persons suffering from glaucoma or increased intraocular pressure unless upon the advice of a physician; and 503(b)(4)—the article was a drug sub-

³ In their briefs both parties refer to *United States v. 42 Jars, etc.* * * * *Bee Royale Capsules*, D.C.D. N.J., 160 F. Supp. 818 (1958) and 162 F. Supp. 944 (1958), and note an appeal pending therefrom in the Third Circuit. In an opinion filed March 12, 1959, the Court of Appeals for the Third Circuit affirmed, deciding the issues identical to those considered in the instant appeal agreeable with the result reached in this opinion, viz: that the action taken by the Post Office Department upon its fraud complaint and subsequent settlement was no bar to the action brought under the Federal Food, Drug and Cosmetics Act, (thus rejecting the proposed rule of "*res administrata*," see note 1, *supra*); that the corporate claimants could not resort to the Fifth Amendment as a basis for refusing to answer interrogatories, and that it was within the trial court's discretion to enter a default judgment under Rule 37(d), F.R.C.P., 28 U.S.C.A., by reason of such failure to answer. Thus, we find ourselves in complete agreement with the Third Circuit although, in our consideration and determination of this case we did not have the benefit of its prior holding.

ject to a 503(b)(1)(B), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: Alva Laboratories, Inc., Chicago, Ill., the manufacturers of the article, appeared as claimant and filed an answer to the libel denying that the article was misbranded as alleged. Interrogatories were thereafter served upon the claimant by the Government. The claimant subsequently filed objections to answering the interrogatories. The matter came on for hearing before the court on 10-15-57, with the result that the court ordered the claimant to answer certain interrogatories and arranged for a further hearing on the matter of answering the remaining interrogatories. The claimant filed answers to some of the interrogatories on 11-14-57. Thereafter, the case remained pending to permit claimant to consider the matter of revising the labeling of the article.

On 5-4-59, the Government filed a motion to amend the libel to include the charge of 503(b)(4), as stated above, and a motion to compel further answers to the Government's interrogatories. The motion to amend the libel was granted on 6-8-59, and the motion to compel further answers to the interrogatories was granted on 8-10-59.

Thereafter, a stipulation signed by the attorneys for the claimant, the claimant's president, and the Government's attorneys was filed consenting to the entry of a decree of condemnation and acknowledging that the article was misbranded when introduced into interstate commerce in that the labeling of the article failed to bear adequate warnings for use in certain pathological conditions, namely, that the article should not be taken by persons suffering from glaucoma or increased intraocular pressure unless upon advice of a physician. Pursuant to such stipulation, the court, on 12-7-59, ordered that the article be condemned and destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6006. Various drugs. (Inj. No. 326.)

COMPLAINT FOR INJUNCTION FILED: 3-31-58, E. Dist. Wis., against Adolph Fictum, t/a Wm. Horner Co., and Wm. M. Horner Co., Green Bay, Wis., to enjoin and restrain the defendant from doing acts resulting in the misbranding of various bulk drugs and repackaged drugs, while held for sale after shipment in interstate commerce, and from introducing and delivering for introduction into interstate commerce, various bulk or repackaged drugs which were misbranded.

NATURE OF BUSINESS: The defendant was engaged in manufacturing, packing, mixing, selling, and distributing, singly and in combination the following drugs:

Wm. M. Horner's Pure Herb Health Tea or Horner's Herb Tea which contained senna leaves, uva ursi flowers, cascara sagrada, Spanish aniseed, licorice root, fennel seed, elder flowers, and dandelion root.

Wm. M. Horner's Ointment for Eczema and Skin Diseases which contained petrolatum, sulfur, oil of tar, creosol, phenol, and olive oil.

Wm. M. Horner's Pure Herb Laxative which contained cascara, cinnamon, cloves, nutmeg, and glycerine.

*See also No. 6005.